



Frequently Asked Questions The Role of Animals in Biomedical Research

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1. Are animals really necessary to biomedical research?

Under federal law and many international treaties and agreements, it is illegal to experiment on humans, and human clinical trials must be predicated on animal studies. According to the Nuremberg Code, drawn up after World War II, any experiments on humans ". . . should be designed and based on the results of animal experimentation." (The Nazis outlawed all animal experimentation, but allowed experiments on prisoners in concentration camps). The Declaration of Helsinki, adopted in 1964 by the 18th World Medical Assembly and revised in 1975, also states that medical research on human subjects "should be based on adequately performed laboratory and animal experimentation." Under the Food and Drug Administration, permission to conduct clinical (human) trials will only be granted after the review and approval of an Investigational New Drug application (IND). This extensive process must demonstrate safety and effectiveness in animal models for FDA review, and approval. No new drug may be marketed in the United States without final approval by the FDA.

Human biological systems are complex, therefore it is necessary to research and test with animals that are similar to humans to obtain reliable and effective results. New drugs, devices, or procedures must receive legal approval from the federal Food & Drug Administration (FDA) before use in humans.

In fact, almost every major medical advancement in the last century is due to research with animals. Research on animals provides necessary information to predict how a new drug or procedure will affect a human. Such medical advancements include, prevention of measles, diphtheria, mumps, whooping cough and polio. Medications to treat mental illness, chemotherapy to treat cancer, antibiotics to treat infectious diseases, heart and cardiovascular surgery, and organ transplants are some of the additional medical benefits from animal research. Scientists must test medical treatments for effectiveness, and new drugs for safety before using them on humans. Small animals especially bred for laboratory use, usually rats and mice, are used to identify any undesired side effects of new drugs, such as infertility, miscarriage, birth defects, liver damage and cancer-causing potential. Once new drugs are proven safe in animal studies, they may be used in clinical studies on human volunteers, who then have the assurance that they may fare better - and will not do worse - than if they were given standard treatment or no treatment at all. New surgical techniques also must be carefully devised and tested in living, breathing, whole organ systems with pulmonary and circulatory systems much like those in humans. The physicians and physicians-in-training who perform today's delicate cardiac, ear, eye, pulmonary and brain surgeries must develop the necessary skills before patients' lives are entrusted to their care. Neither computer models, cell cultures, or artificial substances can yet simulate flesh, muscle, blood, bone and organs working together in the living system. If we were to abolish the use of live animals entirely, we would be unable to investigate the effects of how one system (for example, the nervous system) interacts with another (for example, the immune system or the endocrine system), while monitoring side effects (effects on respiration, kidney function, or heart rate). For specific examples, read about research on birth defects and implications for microsurgery.

2. Isn't animal research scientific fraud, since animals and humans are so different?

There are many similarities between humans and various species of animals. For example, much of what we know about the immune system has come from studies with mice. Cats have helped us know more about sleep disorders such as SIDS, sleep apnea and epilepsy. Cats represent *less* than 1% of animals used in research. Their contributions are valuable, not only to humans but to the feline population. Vaccines for feline leukemia and feline distemper were developed using cats. Other studies involving cats cover vision disorders (such as lazy eye), the nervous system, and toxoplasmosis, which is caused by a parasite that can infect humans. Dogs also represent less than 1% of animals used in research. A vaccine for canine parvovirus was developed using the dog model. This animal has contributed to our understanding of diabetes and to the development of the heart-lung machine and the first successful kidney transplant. Much of what we know about the human heart and lungs has come from studies with dogs. Primates share 98% of human genes. Much of what we know about the brain, heart disease, Alzheimer's Disease, AIDS, viruses, hepatitis and cancer has come from monkeys and chimpanzees. Mice have contributed to our understanding of cancer, aging, and immunology (including AIDS). Rats are used as models for Alzheimer's Disease, hypertension, diabetes, cancer, and dental studies. Rabbits have contributed to studies involving the immune system, eyes

and ears, and cholesterol. Pigs have hearts very similar to ours, which has led to the development of new drugs for heart disease. Pigs have also contributed to studies on skin disease and burn treatments. Primate research has led to many valuable medical breakthroughs. The polio vaccine was developed using primates, as was the treatment of the Rh factor. Other research areas involving primates include malaria, heart disease, and dental research. Sheep were used in finding a vaccine for anthrax. This is a bacterial disease that affects cattle and can be transmitted to humans. Sheep are also models for treatment of kidney failure. Woodchucks are used in studies of Hepatitis B. This viral disease not only affects humans, but animals and wildlife. Guinea pigs are used in nutritional studies as well as studies of the immune system. Fish (many species) are used in studies of liver cancer, diabetes, immune systems, vision, and heart disease.

3. Do laboratory animals suffer pain?

The use of animals in research and testing is strictly controlled. Veterinarians and their staff are very involved in the care and treatment of laboratory animals. Their job is to ensure that the animals are given proper drugs to eliminate pain or discomfort. Researchers realize the use of animals is a privilege, and those animals that are helping us unlock the mysteries of disease, deserve our respect and the best possible care. Also, a healthy and well-treated animal will provide more reliable and valid scientific results.

4. Are animals abused and mistreated?

Poor animal care is bad research. In addition, mistreatment of animals can cause government agencies to fine and/or close down a research facility. Research funds could be stopped. A researcher convicted of cruelty to animals can be suspended or dismissed, fined or even jailed. The animal rights movement usually relies on a handful of instances that occurred in the 1970s and early 1980s to bolster their claim that animals in research are being abused 'behind closed doors' at a medical facility. Federal legislation on the 1980s significantly strengthened the rules and regulations of animal care to prevent this. In fact, many of the pictures of animals depicted in 'alleged abused situations' are actually cases where the incidents were staged or the pictures were manipulated. In addition, pictures depicting routine animal care, such as spaying and neutering, are also used as pictorial "evidence" of animal experimentation. The fact is, in thousands of studies and experiments since 1980, NIH found only 14 instances in which sanctions were warranted. These sanctions ranged from investigator or institution reprimands, to suspension or loss of NIH funds. In that period, NIH suspended funding to four institutions. To date, only two projects ("Silver Spring Monkeys" study and a University of Pennsylvania baboon head injury project) have been terminated. Neither researcher involved in these cases was convicted of cruelty to animals.

5. Aren't millions of stolen pets used in research?

A total of 75,000 dogs and 26,000 cats were used for education and research in 1998 in all research facilities in the United States. Approximately 50 percent of these animals were purpose-bred for research by United States Department of Agriculture (USDA) Class A Dealers and 35 percent were purchased from licensed USDA Class B dealers. Only the small remainder were obtained from pounds or shelters. USDA dealers must be licensed and follow rules by the USDA. Also, the government often inspects the dealers and research facilities to make sure research animals are not missing pets. Very few states allow dogs to be purchased for research from animal shelters or the pounds or from unlicensed dealers, the only source for the potential for domestic pets to enter research. According to the American Humane Association, between 8 to 10 million unclaimed dogs and cats are euthanized at the pounds and shelters each year because they were abandoned by their owners and not adopted. In few instances, some animals already scheduled to be killed by the pound or shelter may be released to research. Laws prohibiting the use of pound animals in research means that additional animals must be specially raised for research use, which increases costs and the total number of animal deaths. Forty percent of dogs and cats involved in research are specifically bred for this purpose. The rest are purchased from highly regulated Class B animal dealers or from pounds, where otherwise the animals would be put to death. The USDA mandates that animals procured from pounds must be held on the pound's premises for five days and on the dealer's premises for additional five or ten days. Therefore, the USDA-mandated holding period is ten to fifteen days, providing ample time for owners to locate lost pets, or for unwanted animals to find new homes. According to Merritt Clifton, editor of the animal rights publication *Animal People*, "...there simply isn't the demand now to sustain a high-volume market for stolen pets in medical research. No demand--no business." For more information of this topic, please see the CBRA Fact Sheet -The Pet Theft Myth.

6. What about the animals' rights?

Biomedical researchers are strongly advocated of animal welfare. It is important to understand the difference between animal rights and animal welfare. Scientists who use animals in research support animal welfare. They are obligated to give the animals respect, and ensure their health and well-being. To do otherwise, would be irresponsible and unethical. Ask yourself the question, "Do you value animals as equal to humans?" Animal rights groups believe animals are equal, or more valuable, than humans. Each of us must decide if we can accept, that in some cases, animals can be studied in research to help scientists find better treatments and cures to improve the health of humans and other animals.

7. Why can't 'alternative' methods replace animal research? Why can't computers replace experiments on animals?

Whenever possible, researchers do use non-animal models. Computer models, cell cultures, and a number of research methods that complement animal studies are used today in biomedical research. Computer models are used to screen and determine a toxic level of substances in the beginning of an experiment. Cell and tissue studies are important adjuncts of biomedical research. More recently, computer models have become valuable additions to the array of research tools and techniques. But living systems are complex. The nervous system, blood and brain chemistry, gland and organ secretions, and immunological responses are all interrelated. It is impossible to explore, explain, or predict the course of many diseases or the effects of many treatments without observing and testing the entire living system. Therefore, final tests must be done on a living model. Blindness cannot be studied in bacteria, nor high blood pressure in tissue cultures. Surgery cannot be simulated on computers. To study many common and often devastating disorders, there is no choice but to work with animals whose organs are similar to those of human beings. In fact, following the recent development of these complementary research models, the USDA reports a reduction in the number of laboratory animals used in research. These computer models and other non-animal models are built using research data generated from earlier animal studies. Without the knowledge gained from this original animal research, non-animal models would have no basis and work not be available. To date, even the most sophisticated technology has not been able to mimic all the complicated interactions among cells, tissues and organs that occur in a living body. Significantly, scientists are bound by law to investigate these interactions before using a new drug or chemical compound in studies with people. In the early stages of a research study, non-animal models are used to predict amounts of a chemical compound that would cause irreversible harm to a live animal. It will then be tested in living animals, and later tested in living people. Incidentally, there are strong economic incentives to substitute research animals with computers or other complimentary non-animal methods *whenever* possible. Research animals are extremely expensive to purchase, house, and oversee during the research study.

8. What other methods are used in addition to animals in research?

Mathematical and computer aids as well as cell, tissue and organ cultures are all useful in the preliminary stages of research. Mathematical models can improve on experiment's design and help predict an organism's response to varying levels of exposure to a particular chemical. Computer data banks offer the ability to share results with other researchers that reduces test duplication. Culture tests can give some information about a compound, but cannot predict how it will affect a living system. The only way to get a complete picture of how a substance or procedure will affect a living system is to test it.

9. Why are animals used for cosmetic testing?

Testing these products on animals is necessary to ensure our safety. Up until 1938, our nation had no product safety testing laws. Consumers took their chances whenever they took drugs, applied cosmetics, or used cleaning products, art supplies, or industrial chemicals. In the 1930s, there were two cases where untested products caused tragedies: an eyelash dye resulted in numerous cases of blindness and at least one death, and a cough remedy caused 107 deaths. Congress responded in 1938 by passing The Federal Food, Drug and Cosmetic Act which required for the first time that all drugs be tested for safety before they are marketed. Today the Food and Drug Administration (FDA) is only one of several federal agencies that regulates the safety of various consumer products and chemicals. Cosmetics are listed under the category of product testing. Product safety testing makes sure that products, such as shampoo, deodorants, sunscreen and household cleaning products are safe when used as directed. The testing provides information for poison

control centers and emergency room doctors in the event a product is not used properly. Using products without first being tested can result in permanent harm, including blindness. Not all product testing involves animals. The federal regulations for the approval of new drugs or pesticides require animal test data, while cosmetic safety laws simply require that product safety be demonstrated. However, even where some animal data are required, animals are used sparingly, and every effort is made to keep the numbers to a minimum. Scientists first review existing data on the chemicals in the product. If their safety has already been established through prior animal testing and safe human use, no further animal tests may be needed. If the ingredients are very similar to ones already in use, non-animal tests using cell or tissue cultures may be all that is needed before proceeding directly to clinical studies with human volunteers. If a product includes new chemicals or involves a different kind of use (i.e., an aerosol spray instead of a skin ointment), then additional animal and non-animal tests may be needed to determine whether the new ingredients or new application pose a danger. Database research and computer analysis of the chemical structure or physical and chemical properties of the new ingredient may be used to predict likely effects. Animal tests are used when neither the existing safety information nor non-animal tests can provide enough information about how the compound could affect human or animal health or the environment.

10. What is meant by "cruelty-free" as written on cosmetics and consumer products?

The "cruelty-free" label is similar to a "low-fat" label in the grocery store, in that the implications are somewhat hidden from the public. Both are marketing strategies to sell a product by making it appear more desirable than another product. A dieter will soon learn he cannot lose weight by simply eating "fat-free" ice cream. He must also make sure the ice cream is low in sugar and low in calories. A woman buying a "cruelty-free" lotion may assume she is using a product that was not tested on research animals, but this claim is also misleading. In reality, all ingredients that make up lotions and cosmetics produced in the U.S. must have at one time undergone safety tests, generally using rodents, as required by federal laws enacted several decades ago. The federal government places high priority on public health and the safety of its residents. Product safety laws help protect us from harm, should these products accidentally get into the eyes or be ingested. Our laws address not only the safety of prescription eye drops, for example, but also the safety of lubricating drops sold over-the-counter without a doctor's prescription. When you see a "cruelty-free" or "not tested on animals" label, one of several scenarios may be true. If a new lotion on the market contains ingredients that were approved years ago by safety studies using animals, the ingredients do not have to be tested again. Safety tests on select naturally occurring ingredients are not always required. If a company manufactures a new product, yet is not involved in the research of that product, it may still consider itself "cruelty free". To learn more about product safety laws, read about the Federal Food, Drug, and Cosmetic Act. Product safety testing also provides scientific information for poison control centers and emergency room physicians in the event a product is misused. Although non-animal models are being developed for product safety tests, the use of animals in product safety testing is still the preferred method by many scientists to demonstrate how substances will react in or on a living body system.

11. Why are animals used for repetitive experiments?

The number of animals used in research has actually decreased by 40 percent since 1968. This is due, in part, to an increase in non-animal testing and the improvement of laboratory animal medicine. Some experiments need to be repeated in order to discover errors and to confirm that the first research results are valid and correct. Experiments must also be repeated to check changes in weight, temperature and dosages. Because of competition for research funding, only the highest priority projects are undertaken. For example, NIH is able to fund only about 25 percent of all scientific proposals it finds worthy.

12. What happens to the animals once an experiment is completed?

Most animals are euthanized (put to sleep) in order to study their tissue. Animals whose tissues are not needed may take part in additional experiments. Most often, the animals are not allowed to take part in more than one major surgical procedure. Other animals are adopted out to families, and many others live their natural lives, cared for in research facilities although they are never again used for research.

13. Isn't animal research just "big business"? It wastes taxpayers' money.

People choose careers in animal research because they want to find answers to complicated questions, not to make money. Most researchers could make more money in other careers. In addition, researchers have

chosen their field by a desire to help others and to relieve suffering. The payoff for research is not money but the treatments and cures that benefit both humans and animals. It is also a common misconception that animals are used because they offer a "cheap alternative" to non-animal techniques. The reverse is in fact true. Research animals are very expensive to purchase, house, feed, and care for. Computers and laboratories equipment would be much *less* expensive, and much *easier* to care for. All medical researchers want the numbers of animals needed for research to continue to decrease and to use as few animals as possible. Currently, however, their role is still crucial.

14. Animal research is not effective. Aren't people still dying of heart disease and cancer?

People today are surviving many forms of heart disease and cancer that were fatal 50 years ago. Today, cancer survival is above 50 percent. And cancers can be cured, for example, leukemia and Hodgkin's disease. Vaccines for melanoma (skin cancer) are prolonging life. Drugs for high blood pressure and improved surgical procedures are saving millions of lives.

15. Why do veterinarians, who pledge to take care of sick animals, work with researchers who experiment on them?

Veterinarians chose their career because of their concern for animals, and they are very involved in the care and treatment of laboratory animals. Consequently, laboratory animals are healthier and more comfortable. Lab animal veterinarians realize that the results of animal research improve the health of animals as well as humans.

16. How has animal research helped our pets and other animals?

The same methods that have been developed to prevent and treat diseases in humans have improved the lives of countless animals. More than 80 medicines and vaccines developed for humans are now used to heal pets, farm animals and wildlife. Pets, livestock, and animals in zoos live longer, more comfortable, and healthier lives as a result of animal research. Animal research has helped develop animal vaccines to fight such animal diseases as rabies and distemper in dogs and cats, feline leukemia, infectious hepatitis virus, rabies, tetanus, treatments for heartworm, therapies for cholera in hogs and preventive techniques for tuberculosis in cattle, and influenza and encephalitis in horses. Where would animal care be today without vaccines against rabies, distemper, feline leukemia, tetanus, parvo virus, infectious hepatitis, and anthrax? Animals have been helped with treatments for artificial joints for dogs, treatments for pet cancer and pet heart disease, antibiotics for infection, and treatments for vitamin deficiency in animal diseases such as rickets. Techniques such as ultrasound and "CAT" scans are commonly used in veterinary medicine today. Animal research has helped preserve nearly extinct species, such as the California condor and the tamarins of Brazil due to new reproductive techniques being applied to endangered species. It has significantly contributed to programs of artificial insemination in species such as elephants, pandas, and other endangered species. In fact, according to *The New York Times*, "Nearly every medical procedure now done on humans is being used or studied for use at the nation's leading companion animal medical centers."

17. Does the use of chimpanzees in research threaten that population?

Most of the non-human primates now used in research are specially bred for that purpose. Chimpanzees have not been imported into the U.S. for research purposes since the mid- 1970's. Today, the major threats to such animals in the wild are deforestation, land use and development - not research. Chimpanzees bred in captivity in the future may be the source for survival of some wild populations.

18. How many animals are used in research?

The best source available estimates that 17 to 22 million animals are used annually in research and testing, according to the Office of Technology Assessment, U.S. Congress. Specially bred for laboratory testing, rats and mice account for 95 percent of all animals used in research. Less than one-quarter of one (.25) percent are non-human primates, and less than one half of one percent (.50) are dogs and cats. The remainder include rabbits, guinea pigs, sheep, pigs, fish and insects. Due to genetic research, laboratory animals can now be bred to mimic some human conditions, including tumors. Species that reproduce quickly and that have genomes that are very similar to humans are especially useful in understanding diseases and in finding treatments for them. Such animal models for human disease allow scientists to use fewer animals to derive

more reliable and faster information than was ever before possible.

19. Where do scientists get their animals?

Most scientists use animals that are specially bred for research. The animals most commonly used in research are rats, mice, and other rodents. These animals are bred for research, and scientists purchase them from animal breeders. Small numbers of other animals are used in research including pigs, sheep, other farm animals, dogs, cats, and primates. Dogs, cats, and primates comprise less than 1% of research animals, and there are special rules about obtaining them for research. For example, primates from threatened species may not be caught from the wild and must therefore come from breeding colonies. The use of primates, dogs, and cats in research is governed by the federal Animal Welfare Act (AWA). The AWA requires that those who sell dogs and cats for research must be licensed and requires that research animals be given proper care. According to the USDA, the number of dogs and cats in research in 1996 is 60% lower than in 1973, the first year these statistics were collected. Approximately 70% of the dogs and cats used in research are bred for research, and the remaining amount are "random source" animals. Researchers may buy purpose-bred animals from USDA-licensed breeders or raise them in their own breeding colonies. Purpose-bred animals tend to be young, share a common genetic background, and be small in size. These characteristics make them suitable for some kinds of research, but unsuitable for others. In particular, when scientists want to study heart disease, organ system failure, bone defects, or joint disorders, they need to use animals that are large, physiologically mature, or even elderly, and that represent a genetically diverse population. Every year, 6-10 million unwanted dogs and cats are killed in our nation's pounds. Less than 1% of these animals would be needed to provide the random-source dogs and cats required for medical research. The AWA permits scientists to obtain dogs and cats for research directly from pounds. Unfortunately, in many places, scientists cannot do so because animal activists have insisted on laws or policies forbidding this. In those cases, scientists must rely upon a second category of USDA-licensed dealers, who handle random-source animals. These dealers are allowed to purchase dogs and cats directly from their owners, from pounds, and from other USDA-licensed dealers. They must comply with special record-keeping and holding provisions to protect against pet theft and to give owners time to recover lost pets. The USDA is diligent about enforcing these provisions. USDA inspectors use dealer's records to check whether the person listed as the owner really did provide the animal. Over the last several years the USDA has issued steep fines against dealers whose records were incomplete or false, and several who were guilty of serious violations were put out of business. According to the March 1998 issue of the animal activist publication *Animal People*, these law enforcement efforts have "virtually halted thefts for laboratory use." No scientist would want to use someone's pet, and the Animal Welfare Act has numerous provisions to make certain that pet dogs and cats do not accidentally end up as research subjects.

20. What laws protect animals in research?

Biomedical research, teaching, and testing are the subject of and controlled by an extensive system of laws, guidelines, and regulations that protect the welfare of laboratory animals in the United States. This extensive federal oversight includes the Animal Welfare Act (AWA), the Health Research Extension Act, and a series of other laws and policies from the various federal agencies involved in the U.S. research effort (EPA, FDA, NSF, etc.). In addition, many facilities and researchers may also be licensed by their state and/or international organizations, depending on the research and teaching they conduct, and the species involved. Some governmental officials even believe there are more laws that govern the use of animals in research than cover the use of human subjects in clinical trials.

The federal Animal Welfare Act (AWA) is the key law governing research with animals in the U.S. The AWA was first passed in 1966 and has been amended several times since (1970, 1976, 1985, and 1990). It mandates that all research facilities (with some exceptions discussed below) register with the U.S. Department of Agriculture (USDA). The Animal and Plant Health Inspection Service (APHIS) within the USDA is responsible for administering and enforcing the AWA and for making at least one unannounced inspection a year to each facility.

While the AWA covers the majority of research animals, it does not cover rats, mice, or birds. The Health Research Extension Act of 1985, however, made Public Health Service Policy the law, and the Public Health Service Policy specifically regulates the care and use of *all* vertebrate animals used in research, testing, and

education, *giving rodents and birds* the same protections given primates, cats, and dogs. In addition, the Health Research Extension Act requires all medical research funded through the National Institutes of Health (NIH) to conform to the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals. The NIH funds more than half of all medical research in the U.S.

The Office of Laboratory Animal Welfare (OLAW), in the National Institutes of Health (under HHS and PHS), significantly oversees laboratory animal care, maintenance, and use. The Institute of Laboratory Animal Resources (ILAR) under the National Academy of Sciences prepares the *Guide for Care and Use of Laboratory Animals*. Most other federal funding agencies also require scientists to use the *Guide for the Care and Use of Laboratory Animals* to determine appropriate standards for animal care.

Research facilities that are registered with the USDA are not required to register with the State of California and other states, signifying the intent of the state to defer to federal regulatory authority in this area. In California, all facilities that are not PHS Assured (they receive no funding from the NIH) and do not have species regulated by the AWA, must register with the State of California. For those outside of California, please consult your specific state regulations as they pertain to research.

In addition to state and federal regulation, most research facilities seek voluntary accreditation by the Association for the Assessment and Accreditation of Laboratory Animal Care International (AAALAC), a private nonprofit organization that promotes the humane treatment of animals in science through a voluntary accreditation program administered by veterinarians specializing in laboratory animal medicine, among other experts. Accreditation is a complex process requiring months or years. Every aspect of an institution's facilities, policies, procedures, and personnel is examined in detail. One of the critical aspects to be considered is the program of veterinary care. Although AAALAC accreditation is voluntary, its benefits are so significant that accreditation is mandatory for all practical purposes in many situations. Some federal agencies, for example, require AAALAC accreditation of an institution to even apply for grants. OLAW has a separate and greatly simplified assurance procedure for accredited institutions.

21. What are some of the medical advances made as a result of using animals in research?

The list is almost endless. Virtually every major medical advance in the past century has depended upon animal research. Some examples are: Vaccines against polio, diphtheria, mumps, measles, rubella, and smallpox; Open heart surgery; Kidney, liver, heart, lung, and pancreas transplantation; Antibiotics and medications for ulcers, mental illness, arthritis, asthma, epilepsy, and high blood pressure; Treatment for many forms of cancer including leukemia, lymphoma, breast cancer, and Hodgkin's disease; Development of artificial blood vessels; Measurements related to stroke recovery; "Clot buster" drugs used for the treatment of heart attack and stroke; Development of treatments for cystic fibrosis; Treatment for pneumonia and influenza; External filtration of blood for patients awaiting liver transplant; Advances in vaccine and therapy for HIV/AIDS. In addition, many of the advances in veterinary medicine are the direct result of research with animals; Rabies, heartworm, feline leukemia, and many other pharmaceutical products used to promote health in animals have been developed as a result of animal research; The parvovirus vaccine, routinely administered by veterinarians, has saved the lives of many dogs; Pacemakers for both humans and animals were developed through research on dogs; Research in reproductive physiology on animals has helped save certain species from possible extinction, like the African wild cat, the California condor, and the panda bear.

22. Why are increasing numbers of animals being sacrificed for research each year?

Actually, the number of animals used in research has decreased in the past 20 to 25 years. Estimates for the reduction in the overall use of animals in research ranges from 20% to 50%. The number of dogs used in biomedical research has declined 67%, and the number of cats used in biomedical research has declined 63% since 1973. One of the primary reasons for this decline is the creation of computer programs and other research methods that are scientifically valid *alternatives* to animal research. There are still vital areas, however, of biomedical research for which these other research methods are unable to replace living organisms.

23. Why do some people still experience side effects after a compound has been found safe in animals?

Even after years of intensive study and a comprehensive evaluation of all the data, medicines sometimes cause unexpected side-effects in general use. Those who campaign against animal research frequently cite such side-effects as an argument against animal testing, but this is to misunderstand the careful step-by-step nature of the research process. No one expects animal studies to provide all the necessary information and final decisions are never made on the basis of animal tests alone. Rather, they enable researchers to move as close as possible to the human situation before a new medicine is tested and used in people. All medicines approved by the FDA, even those later found to have unexpected side effects, passed all the testing stages including non-animal, animal, and human trials. No amount of testing can guarantee to find all of the possible side-effects for every person who may take a medicine. A reaction which occurs at a rate of 1 in 100,000 people or even at a higher rate of 1 in 10,000 for instance, may not be seen until very large numbers of people use the medicine. On the other hand, no human being should ever be put at risk because of a reluctance to do the necessary and adequate testing on animals prior to human use.

24. Do researchers care about the animals they use?

Researchers are no different from other people in their attitudes toward animals. Scientists are concerned about their research animals, both for humane reasons and because healthy test animals are necessary for valid research results. Stressed animals don't yield reliable data. In addition, the scientist's commitment to animal welfare means ensuring the well-being of his or her research animals. That is why researchers are constantly looking for ways to provide enrichment for animals in their care. This can be something as simple as a food supplement or toys or it could mean changing their enclosures to allow the animals to socialize.

25. Why test on animals instead of humans?

Research on animals is in many cases an obligation. U.S. law *requires* pre-clinical trials of drugs and medical devices on animals *before* human trials are allowed. The FDA will not approve any such item for use in the general public *without* animal trials. No animal testing means no new drugs. In addition, international treaties and agreements require it as well. According to the Nuremberg Code, drawn up after World War II as a result of Nazi atrocities, any experiments on humans "should be designed and based on the results of animal experimentation." (The Nazis had outlawed animal experimentation but allowed experiments on Jews and asocial persons.) The Declaration of Helsinki, adopted in 1964 by the 18th World Medical Assembly and revised in 1975, also states that medical research on human subjects "should be based on adequately performed laboratory and animal experimentation."

It should be remembered, however, that not all compounds are tested on whole animals before being tested on human beings. In some instances, *in vitro* techniques are a perfectly suitable substitute for whole animals. For example, *in vitro* techniques might be used to determine whether a reformulated topical antibacterial ointment or sunscreen is likely to cause skin irritation in humans, and if so how much. If the compound passes the *in vitro* test, it might then be tested directly on humans without first using whole animal. Second, humans are used extensively in tests. Studies of this sort are called "clinical trials" and there are usually no fewer than three clinical trials prior to a compound being approved by the FDA. The first clinical trial is composed of a small group of volunteers. If the compound is shown to be safe and effective with this group, it is then tested in a second group that is larger than the first. If the results from the second group are positive, it then moves to the third clinical trial that usually involves a very large group of volunteers. It is only after passing through this extensive testing process that includes both human and animal testing that a compound will be approved by the FDA for general use.

There are, of course, philosophical and ethical issues to consider. On the most basic level, most of us believe that it is important for medical doctors to understand the healthy body and diseases as well as other health-related conditions that can diminish our quality of life (trauma, aging, birth defects are some examples). In conducting research to further this understanding, the best model for research must be considered. Should we use whole living animals when acceptable alternatives exist? Most people would say no. And most people would say that it is unethical to use human beings as the initial experimental subjects for many types of basic research (especially those requiring invasive procedures), or for the initial "whole animal" tests of promising

compounds whose direct effects and side effects can not be predicted with reasonable confidence from in vitro studies alone. Even with the animal testing that takes place today, a recent survey reported in *Time* magazine (April 27, 2002) found that 79% of all those polled said people were "gambling with their health" when they participated in clinical trials.

26. How does laboratory animal research teach health professionals, medical professionals and scientists more than what is already known about the human body, injuries and diseases?

There are striking similarities between the body systems of humans and various species of animals. For example, much of what we know about the immune system has come from studies with mice, and much of what we know about the heart and heart disease treatment and surgery has come from studies with dogs. In fact, virtually every major medical advance of the last century is due, in part, to research with animals. Laboratory animal testing is also required by our federal government to first provide necessary information that is then used to design studies using men, women and children as research subjects. It is important to gauge how a new drug or medical procedure will affect an entire living body system before using it on humans. All new medical devices, medical drugs and medical procedures must undergo a scientific peer review, plus a lengthy legal process of being tested with laboratory animals, followed by testing with people.

27. What role do veterinarians play in medical research with animals?

Veterinarians, who have chosen their profession because of their concern for animals, are intimately involved in the care and treatment of laboratory animals. They realize that results of animal research improve the health of animals as well as the health of people. Many advances in veterinary medicine are the direct result of animal research. The Parvovirus vaccine has saved the lives of many dogs. Heart pacemakers for both humans and animals were developed through research using dogs. Studies on animal reproductive physiology have helped prevent certain endangered species from reaching extinction. Distemper vaccines, tested on Siberian polecats, resulted in the revitalization of the once disappearing black-footed ferret population. Veterinarians are also charged, by federal law, with the primary role of directing animal care and use programs for institutions that perform research with animals. The program must include the training of animal research scientists in the humane and responsible handling of research animals. The veterinarian also advises an internal review committee in the approval of all research protocols before animals may be studied. Staff under the veterinarian may include licensed veterinary medical technicians.

28. Are there any laws that prevent research animals from unnecessary pain during the research study?

The use of research animals is strictly controlled, especially when there is the possibility of pain as a result of the study. The Animal Welfare Act was passed first in 1966 and has been amended a number of times since then. Animal comfort is addressed from birth through shipping, housing and feeding, the duration of the research study, and the animal's death. Clauses in the Act also address exercise for dogs and psychological well-being for primates. Each research institution must establish an animal care and use committee that includes a member of the general public, such as a local veterinarian, church minister, or employee of the Society for the Prevention of Cruelty for Animals. Membership on this committee must also include a veterinarian with specific experience in laboratory animal care. This committee reviews, approves (or disapproves), monitors, and inspects every research study to help ensure that animals are not subject to unnecessary pain and distress. Review committees are charged with keeping abreast with, and requiring research scientists to use, state-of-the-art methodology of preventing pain in laboratory animals. For instance, an animal that undergoes a surgical operation, according to approved study, is now given pain medication that will last after the surgical anesthetic has worn off and the animal wakes up. The animal is spared immediate post-operative pain, and also spared pain during the recovery period. In contrast, small animal veterinarians in private practice don't always give post-operative pain medication to a pet dog or cat that has just been spayed or neutered. In general, state-of-the-art procedures are introduced into laboratory animal medicine long before procedures become routine in private practice. Interestingly enough, research studies have also demonstrated that when animals do not feel pain, they provide more reliable scientific results.

29. What is the difference between "animal rights" and "animal welfare"?

"Animal rights" is the belief that animals are not ours to use—for food, clothing, entertainment, or

experimentation. There are dozens of animal groups in the U.S. They vary greatly in type of opposition to the varying uses of animals and in how they oppose these uses. Some groups only oppose using animals in research, some oppose the use of animal products in clothing (leather shoes, fur coats, wool sweaters, silk shirts, etc.) Methods of protest vary from educational outreach in elementary schools, to protests, to boycotts, to vandalism, arson, harassment, and physical attacks. In the spring of 2002, the FBI declared two groups, the Animal Liberation Front and the Earth Liberation Front, as the top two terrorist groups in the U.S.

Animal welfare is a term that sprang up after the federal Animal Welfare Act passed in 1966. The term is used by research compliance inspectors employed by the government, and veterinarians and scientists employed by companies, hospitals, and universities that perform animal research, all of whom are charged with ensuring that detailed regulations are followed when using animals in research. People who promote animal welfare condone the controlled use of animals in research under the strict guidelines of the Animal Welfare Act and its numerous Amendments. Proactive animal welfare advocates also adopt the same high standards for the use of rats, mice, and birds in research, which are not presently included in the Animal Welfare Act.